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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,198	10/10/2001	Eugene O. Major	2370-81	5423

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EXAMINER

WITZ, JEAN C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/22/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,198

Applicant(s)

MAJOR ET AL.

Examiner

Jean C. Witz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other:

DETAILED ACTION

Election/Restriction

Claims 11-15 and 17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 8.

Claim Rejections - 35 USC § 112

Claims 1-10, 16 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a mammal having a neurological syndrome or disease characterized by a dopamine deficiency comprising implanting into said mammal a therapeutically effective amount of a nontumorigenic and noninflammatory immortalized human neuro-glial cell line capable of inducing neuromigration and/or neurite extension in the mammal, does not reasonably provide enablement for treating a neurological disorder with an immortalized human neuro-derived fetal cell line. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification discloses the treatment of a neurological disorder caused by a lesion in a host's central nervous system. This claim language reads on lesions formed by tumors, aneurism, thrombi, and lesions as a result of viral and prion activity, and includes conditions which are considered untreatable such as rabies and Creutzfeldt-Jakob disease. There is no correlation between the showing of the specification and

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the conditions recited above. Further, this lack of correlation is even more evident when applied to the other conditions Applicants allege to be treatable with the claimed method. With regard to Alzheimer's dementia, this condition is due to a degeneration of cells in the basal forebrain, cerebral cortex and other brain areas and is characterized by neurofibrillary tangles. Here, acetylcholine-transmitting neurons and their target cells are particularly affected. Alzheimer's dementia may be confused with other dementias such as senile onset dementias and multiple infarct dementias and diagnosis, a matter of clinical judgment, is usually only confirmed upon autopsy. Huntington's chorea is characterized by an atrophy of caudate nucleus and decreased in both GABA and Substance P. Diagnosis is now available via genetic screening but the disease is insidious, progressive and untreatable. ALS is a motor neuron degeneration with no known treatment and MS involves demyelination throughout the brain, and while often remittent, ultimately progressive and fatal. These neurological disorders represent a myriad of diverse conditions requiring different treatments. It is not predictable based upon the disclosure of the specification that these conditions may be successfully treated by the practice of the claimed invention. Further, there is no showing that the neuronal migration and neurite outgrowth can successfully result in the treatment of any of these conditions. The showing of record is insufficient to support claims to support claims to the treatment of disease or conditions of the central nervous system.

In essence, Applicants assert that one of ordinary skill in the art would, upon reading the specification, be able to therapeutically treat not only Parkinsonism but also

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such diverse conditions such as Alzheimer's dementia, Huntington's chorea, ALS, and MS without undue amounts of experimentation and with a reasonable expectation of success. Given the overwhelming disclosure of the state of the art of the myriad of varied etiologies associated with these conditions and the recognized lack of treatment and in view of the limited showing of Applicants' disclosure, the practitioner in the art would be unable to correlate neurite outgrowth of dopaminergic neurons in healthy monkeys to a therapeutic treatment of the claimed conditions without engaging in an undue amount of experimentation nor would said practitioner have a reasonable expectation of success.

Claim Rejections - 35 USC § 112

Claims 1-10, 16, and 18-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The cited claims are deemed to be vague and indefinite as the claims fail to recite an intended method; the phrase "A method of treating a host" fails to define any condition or parameters by which one skilled in the art would identify such a host. Further, use of the term "host" is unclear as there is no parasitic or commensal organism disclosed for which one would require a host. Also, none of the claims contain any recitation of effective amount. In claims 3 and 16, it is unclear what is meant by the phrase "derived from" as it appears that the cells to be implanted are those of the SVG cell line.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 16 and 18-23 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over WO 91/06631.

The claims are drawn to the treatment of an individual suffering from various conditions of the central nervous system and specifically Parkinsonism by the administration of an immortalized human neuro-derived fetal cell line, specifically human fetal astrocytes.

WO 91/06631 discloses the use of "activated", i.e. immature, astrocytes which have been immortalized for the administration into the brain of a subject for the purpose of treatment of nerve injury or disorder. See page 28 where Parkinsonism is particularly

disclosed. At page 25, embryonic, i.e. fetal, human astrocytes are particularly disclosed. At pages 30-32, the modes of delivery are distinctly disclosed along with the use of polymer implants. Based upon this disclosure the reference is deemed to anticipate the cited claims; in the alternative, the implantation of an immortalized fetal neuro-derived cell line would have been obvious to one of ordinary skill in the art as is noted that Applicants disclose at page 4 of the specification that "only one immortalized human fetal neuro-derived cell line has been reported, however." This cell line is a glial cell line immortalized via SV40 viral transformation which is called SVG and is the same cell line as claimed by Applicants. Glial cells are brain cells which are cell not directly involved in neuronal transmission but act as support cells. There are six categories of glial cells, of which astrocytes is one type which help regulate the passage of molecules from the blood to the brain. Silver discloses the use of immortalized astrocytes, i.e. glial cells, for implantation into the brain such that lesions caused by injury or disease may be treated. Conditions such as Parkinsonism, Huntington's Disease, Alzheimer's Disease and ALS are specifically disclosed as being treated in this manner. The reference also shows that plating neurons in the presence of astrocyte conditioned media promotes neurite outgrowth (Table V, page 69). Per Applicants' admissions, the existence of an immortalized human glial cell line was well known, and in fact, per their disclosure, the only one known. Therefore, in view of the teaching of the reference that immortalized glial-type cells, i.e. astrocytes, are effective upon brain implantation for a number of different neural conditions, the selection of the (only) known human immortalized neural-derived glial cell line would have been well within the skill of the practitioner.

Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 16 and 18-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,690,927. Although the conflicting claims are not identical, they are not patentably distinct from each other because the treatment of a neurological disease or condition associated with a dopamine deficiency falls within the scope of the claimed invention and the treatment of Parkinsonism, which is disclosed as being associated with a dopamine deficiency.

Conclusion

This is a continuation of applicant's earlier Application No. 08/779661. All claims are drawn to the same invention claimed in the earlier application and could have been

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finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

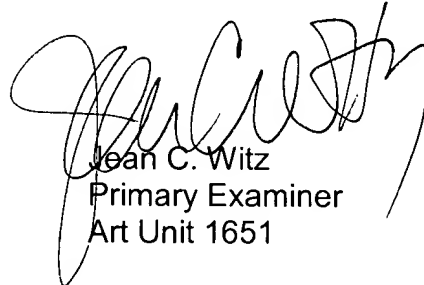
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz
Primary Examiner
Art Unit 1651

April 18, 2003